

## REMARKS

### I. Rejections under 35 USC §102(b)

Claims 7, 10-14 and 17-19 have been rejected under 35 USC §102(b), as being anticipated by Ferguson, US Patent No. 5520926. It is the Examiner's position that the teaching in Ferguson of the use of mannose-6-phosphate to treat fibrotic disorders anticipates the present claims relating to the use of the use of the same material to stimulate the production of glycosaminoglycans in skin, and the treatment of conditions associated with reduced levels of glycosaminoglycans, such as skin aging (chrono-or photoaging), wrinkles and the like. In particular, the Examiner notes that Ferguson, in column 4, lines 28-31, states that the claimed invention is

... primarily of interest in relation to skin wounds, whether arising through surgery or otherwise, including severe abrasions, laceration and burns, but is also applicable to fibrotic disorders, which includes photodamage.

Left out of the Examiner's quotation from Ferguson, however, is the following parenthetical phrase, characterizing the term "photodamage": which is believed to up-regulate certain effectors of an increase in fibrous tissue". The significance of the phrase will be further discussed below. It is the Examiner's position that such treatment in Ferguson is equivalent to the treatment of photoaging in the present claims.

Applicants respectfully disagree with the present rejection, since it fails on both technical and legal grounds. First, it must be noted that the fibrotic disorders referred to in Ferguson are characterized by an excess of fibrous material in the skin. Fibrosis by definition is an excess of fibers in any organ, and Ferguson explicitly associates "photodamage" with an "increase in fibrous tissue". This is significant, because wrinkles and lines that are the symptoms of photoaging, as opposed to the photodamage of Ferguson, are well-established as being conditions associated with a reduction of fibers, namely collagen and elastin, in the skin (see, for example, the attached summary of factors that cause skin aging and wrinkles). Clearly, then, Ferguson is not achieving, or even suggesting, the treatment of lines and wrinkles, because the very purpose of the Ferguson method, and presumably the result, is to reduce the amount of fibers in the treated skin; this is in direct contrast to Applicants' goal in treating or preventing photoaging, which seeks to increase the fibers in the skin to reduce lines and wrinkles. Therefore, whatever the "photodamage" Ferguson's treatment refers to, it is not the lines and wrinkles associated with photoaging. Therefore, from a strictly technical point of view, there is no anticipation of the present claims by the Ferguson reference.

Similarly, from a legal point of view, should the implicit basis of rejection of the claims be an assertion of inherency, this also fails. For the concept of inherency to apply in an anticipation rejection, the subject matter being claimed must undeniably and irrefutably flow from the prior art disclosure. *Hughes Aircraft Co. v. United States*, 8 USPQ 2d 1580 (Ct. Cl. 1988). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Oelrich and Divigard*, 212 USPQ 323 (CCPA 1981). Clearly, the application of mannose-6-phosphate to skin in need of prevention of fibrosis, or excess fibers, as described in Ferguson, would not anticipate the application to skin afflicted by a skin condition in which a depletion of fibers is characteristic, as in the present invention. Therefore, the result claimed in the present application would not "irrefutably flow" from the disclosure of Ferguson.

It may be that the basis of the Examiner's position is that because in both Ferguson and the present invention, the same material is applied to skin, and therefore, the results must be the same. However, the teachings of the present invention, as well as the claims, are much more specific than that, in that they expressly address applying the mannose phosphate to skin and skin conditions in need of increasing glycosaminoglycans, and specifically photoaged skin, which is in need of an increase in fibers, rather than a decrease in fibers as is achieved in Ferguson. Because the present invention addresses application of the mannose phosphate to a type of skin different from that disclosed in Ferguson, then there can be no anticipation of the present claims by Ferguson. See *Perricone v. Medicis Pharmaceutical Corporation*, slip op. (CAFC, 05-1022-1023, December 2005).

In view of the technical and legal arguments presented above, it is clear that the rejection of claims 7, 10-14, and 17-19 as anticipated by Ferguson is improper and should be withdrawn.

II. Conclusion

Claims 1 and 4-6 have been allowed. In view of the arguments provided above, it is believed all remaining claims are also shown to be patentable. With the submission of claims and amendments herein, the application is in condition for allowance, and the issuance of a Notice of Allowance is therefore respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

Respectfully submitted,

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[http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Ageing\\_the\\_skin?open](http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Ageing_the_skin?open)



## Ageing - the skin

The skin is one of the first body parts to show age. While many of these age-related changes are inevitable, some can be reduced with healthy lifestyle choices and good skin care. Many people accept that changes to their skin are part of the normal ageing process. If, however, you want to try one or more of the anti-ageing treatments on offer, consult with an experienced cosmetic dermatologist and make sure you understand all the potential risks, complications and side effects of the treatment.

### Skin layers explained

The uppermost layer of the skin is called the epidermis. This layer contains pigment-producing cells (melanocytes) that give skin its colour. New epidermal cells are born in the basal cell layer of the epidermis - the living layer of the epidermis. The stratum corneum, also known as the 'horny layer', is the outer layer of the epidermis. It contains keratin and is made up of dead cells. Cells of the epidermis start in the basal cell layer and then gradually rise to the surface, while older dead cells are sloughed off.

Beneath the epidermis is the dermis, which contains blood and lymph vessels, nerves, sweat glands and oil glands. Hair follicles are extensions of the epidermis into the dermis. The dermis is made up of networks of elastic fibres (elastin) for suppleness and dense fibres (collagen) for strength. Finally, a layer of fatty tissue lies below the skin and gives it structure.

The skin is one of the first body parts to show age and, while many of these age-related changes are inevitable, some can be reduced with sensible lifestyle choices and good skin care.

### Signs of ageing

Some of the signs of ageing skin can include:

- **Thinning** - the basal cell layer of the epidermis slows its rate of cell production and thins the epidermis. The dermis may become thinner. Together, these changes mean skin is more likely to crepe and wrinkle.
- **Sagging** - older skin produces less elastin and collagen, which means it is more likely to sag and droop. Older skin is particularly vulnerable to the effects of gravity - for example, jowls along the jaw and bags under the eyes are simply skin that has yielded to gravity.
- **Wrinkles** - reduced elastin and collagen, and the thinning of skin, mean those 'high traffic' areas of the face (like the eyes and mouth) are especially prone to lines and wrinkles.
- **Age spots** - the remaining pigment cells (melanocytes) tend to increase in certain areas and cluster together, forming what's known as age or liver spots. Areas that

have been exposed to the sun, such as the backs of the hands, are particularly prone to age spots.

- **Dryness** - older skin has fewer sweat glands and oil glands. This can make the skin more prone to dryness-related conditions, such as roughness and itching.
- **Broken blood vessels** - blood vessels in older, thinner skin are more likely to break and bruise. They may also become permanently widened. This is commonly known as broken vessels.